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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,827	09/12/2003	Andreas Hartlep	SCHWP0177USA	7728

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EXAMINER	
CHAO, ELMER M	

ART UNIT	PAPER NUMBER
3737	

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09/04/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,827	HARTLEP ET AL.	
	Examiner	Art Unit	
	Elmer Chao	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 18-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 September 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Acknowledgement is made of the amendment filed 2/22/2007.

Response to Amendment

2. The amendment filed 2/22/2007 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Claims 1 and 18 recite: "before infusion of a fluid into the tissue". This limitation is not directly supported by the original disclosure. Applicant is required to cancel the new matter in the reply to this Office Action.

Response to Arguments

3. Applicant's arguments filed 2/22/2007 have been fully considered but they are not persuasive.

4. Regarding Applicants' arguments with respect to the 35 U.S.C 102 and 103 rejections of claims 1, 18, and all dependent claims therefrom, Examiner asserts that Kucharczyk '316 would still meet the limitation of "before infusion of a fluid into the tissue". Specifically, Applicants are directed to Kucharczyk '316, claim 8. The fact that Kucharczyk '316 teach in one embodiment that the material delivery device is relocated to improve delivery of material to a desired location would satisfy the instant application's limitation of "capturing via an imaging system function anatomical data

and/or structural anatomical data before infusion of a fluid into the tissue". The infusion of "a fluid into the tissue" under the Kucharczyk '316 reference would refer to the fluid that is delivered after the relocation of the material delivery device. Furthermore, the newly added limitation is not absolutely supported by the original disclosure (see above section Response to Amendment).

Drawings

5. The informal drawings are not of sufficient quality to permit examination. Accordingly, replacement drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to this Office action. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action.

Applicant is given a TWO MONTH time period to submit new drawings in compliance with 37 CFR 1.81. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a). Failure to timely submit replacement drawing sheets will result in ABANDONMENT of the application.

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figure 1 contains hand-written numerals and text. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The

corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. **Claim 16** is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A "computer program" does not fall within any of the four types of patent eligible subject matter (process, machine, manufacture, or composition of matter). Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. **Claims 1-12, 16, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kucharczyk et al. (U.S. 6,026,316).**

Regarding **claims 1, 16, and 21,** Kucharczyk '316 discloses a method for identifying advantageous and non-advantageous infusion regions in a tissue (Fig 7, 4th box down), said method comprising: capturing via an imaging system structural

anatomical data before infusion of a fluid into the tissue (Fig 7); evaluating the captured structural anatomical data with computer assistance (the methods of Fig 7 inherently require computer assistance); and based on the evaluating step, identifying direction channels within the tissue and determining infusion distribution information related to the identified directional channels, the identified direction channels and/or infusion distribution information being indicative of advantageous and/or non-advantageous infusion regions; presenting identified advantageous and/or non-advantageous infusion regions for viewing by a user; and identifying transport pathways based on the diffusion measurements (Fig 7, 4th and 5th boxes down, the MRI images would identify all of the diffusion details).

Examiner asserts that Kucharczyk '316 would meet the limitation of "before infusion of a fluid into the tissue". Specifically, Applicants are directed to Kucharczyk '316, claim 8. The fact that Kucharczyk '316 teach in one embodiment that the material delivery device is relocated to improve delivery of material to a desired location would satisfy the instant application's limitation of "capturing via an imaging system function anatomical data and/or structural anatomical data before infusion of a fluid into the tissue". The infusion of "a fluid into the tissue" under the Kucharczyk '316 reference would refer to the fluid that is delivered after the relocation of the material delivery device.

Regarding **claim 2**, Kucharczyk '316 discloses the method as set forth in claim 1, wherein evaluating the captured structural anatomical data includes simulating a distribution of an infusion at a plurality of regions in the tissue (Fig 7, last box, "Repeat

drug delivery as necessary"; also claim 8, "...delivery device relocated to improve delivery of material to desired location," which is equivalent to simulating the delivery distribution in a plurality of regions).

Regarding **claim 3**, Kucharczyk '316 discloses the method as set forth in claim 1, wherein the determined infusion distribution information includes direction information and velocity information relating to infusion regions in the tissue (C8, L61-65, "...distribution kinetics..."; C9, L56-60, "...spatial (direction) distribution kinetics..."; C7, L7-10); Fig 11, graph shows different areas and the relative speeds of diffusion in the areas).

Regarding **claims 4, 10, and 11**, Kucharczyk '316 discloses the method as set forth in claim 1, wherein the structural anatomical data is evaluated two-dimensionally with respect to the distribution information which it contains, and wherein a number of two-dimensional data sets on the functional or structural anatomical data are combined to obtain three-dimensional information (C22, L63-65; "...echo weighted scans...nominal voxel.").

Regarding **claims 5 and 12**, Kucharczyk '316 discloses the method as set forth in claim 1, wherein the structural anatomical data is captured and evaluated three-dimensionally with respect to the distribution information which it contains (Fig 7, 2nd box down; C23, L45-46).

Regarding **claim 6**, Kucharczyk '316 discloses the method as set forth in claim 1, further comprising: evaluating the structural anatomical data over a period of time with respect to the distribution information; And making adjustments in the distribution

information, said adjustments being responsive to structural conditions which have changed over the period of time (Fig 7, boxes 5-7 down from the top).

Regarding **claims 7 and 8**, Kucharczyk '316 discloses the method as set forth in claim 3, further comprising: identifying regions of rapid diffusion (Fig 10, "...along fibers, rapid transport"), determining isotropy and anisotropy of flow directions in the regions in the tissue (Fig 10, "...anisotropic...isotropic..."; C23, L41-50).

Regarding **claim 9**, Kucharczyk '316 discloses the method as set forth in claim 1, further comprising: calculating a distribution volume for an infusion fluid from the functional or structural anatomical data (C7, L6-11, "..signal intensity within MR images ... are indicative of ... delivery volumes.").

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. **Claims 13-15, 18, and 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kucharczyk '316, in view of Gillies et al. (U.S. 6,272,370).

Regarding **claims 13, 14, 18, and 19**, Kucharczyk '316 discloses all of the above limitations. Kucharczyk '316 does not disclose the infusion at the selected point being planned using stereotactic planning and navigation. However, Gillies '370 teaches the use of stereotactics in combination with magnetic resonance imaging in the planning

and navigation for drug delivery (abstract). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Kucharczyk '316 to use Gillies' '317 method to perform the infusion after the infusion site has been selected. Such a modification would produce a method of drug delivery that is more accurate and less damaging to other areas around the target area (C10, L1-9).

Regarding **claim 15**, Kucharczyk '316 uses the acquired anatomical tissue data (Fig 7, 2nd box down) combined with distribution information (Fig 7, 4th box down) for planning the navigation (claim 8; Fig 7, last box down).

12. **Claims 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kucharczyk '316, in view of Gillies '370, and further in view of Strommer et al. (U.S. 6,233,476 B1).** Kucharczyk '316 and Gillies '370 disclose all of the above limitations. Kucharczyk '316 and Gillies '370 do not explicitly disclose the imaging device, processor, and the medical planning and navigation system being connected together. However, Strommer '476 teaches a medical positioning system in which the processor, imager, and navigation system are all connected together (C4, L46-55). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify Kucharczyk's '316 and Gillies' '317 apparatus wherein the imaging device, the processor, and the medical planning and navigation system are connected to each other. Such a modification would allow for the location of the catheter or infusion device to be located and superimposed on the image obtained from the imager (C4, L46-55). Kucharczyk '316 does imply the necessity of the processor, imager, and navigation system to all be connected together because of the method of

"superimposing drug delivery map on anatomic map of target tissue..." (Fig 7, 8th box down).

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elmer Chao whose telephone number is (571)272-0674. The examiner can normally be reached on 9am-4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EC
8/24/2007

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